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Practitioner's Docket No. 1030.004 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Michael Snyder, et al.	Conf. No.: 1863
Application No.: 10/821,745	Examiner: Ghali, Isis
Filed: April 9, 2004	Art Unit: 1615

For: SUSTAINED RELEASE SURGICAL DEVICE AND METHOD OF MAKING AND USING THE SAME

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Following a Final Office Action dated May 25, 2010, Applicants submit the present Request for Formal Review, by a panel of Examiners, of the legal and factual basis of the rejections pending in the present case, in accordance with the Pre-Appeal Brief Conference Pilot Program[1]. Applicants believe that the issues presented are well posed for appeal, and request formal review prior to appeal on the following grounds:

BACKGROUND SYNOPSIS OF SUBJECT MATTER

The present claimed application relates to a glaucoma shunt device that is implanted in an eye and aids the eye in reaching a desired intraocular pressure, while also providing an erodable sustained release medium that assists in treatment. The erosion helps to dynamically achieve the desired ocular pressure.

[1] Official Gazette of the United States Patent and Trademark Office, vol. 1296, Number 2, (July 12, 2005).

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

The office action rejected claims 11 and 21, 24-26, 32, 33, and 38 as being unpatentable over Smedley (7,163,543) in combination with Peyman (7,354,574). The office action rejected claims 22, 27, and 28 as being unpatentable over Smedley and Peyman and further in view of Bardenstein (4,743,255). Claims 23, 29-31, 34-37, and 39 as being unpatentable over Smedley and Peyman and further in view of Wong (6,692,759) as applied to claims 23, 29-30, 36, and over the combination of Smedley, Peyman, and Bardenstein further in view of Wong as applied to claims 31, 34-35, 37, and 39. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1790).

Incorrect Fact Findings and Lack of Evidence

The office action rejected claims 11 and 21, 24-26, 32, 33, and 38 as being unpatentable over Smedley (7,163,543) in combination with Peyman (7,354,574). The office action alleges that claim 11 is obvious in view of Smedley and Peyman. The office action; however, has failed to show where each and every element of the device in claim 11 is taught by the references of record. The office action alleges that claim 11 is obvious in view of MPEP § 2144.04(IV)(B) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Applicants respectfully disagree that claim 11 is obvious in view of Smedley and Peyman in view of *Dailey*. In *Dailey*, the court discusses two prior art references for a nursing container. The court states that, "one of ordinary skill in the art would find it obvious to use the slit nipple of Blanchett in the collapsible container of Matzen in order to achieve intermittent flow responsive to sucking." The court after performing this fact finding and presenting facts as to where every element of the claim was taught by a prior art reference concludes that it would have been obvious for one skilled in the art to have combined Blanchett and Matzen to arrive at the claimed invention. The office action has **not** performed the fact finding that the court performed in *Dailey*. The office action has **not** presented any facts as to where any reference teaches "**a lumen section that extends into the eye and wraps generally circularly around the cornea**." Without performing the required fact finding the office action cannot come to the conclusion that claim 11 is obvious. Moreover, ("'[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'")…. *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

The advisory action issued on August 6, 2010 acknowledges the argument presented above; however, again fails to present any facts as to where this element is taught by a reference of record. Specifically, the advisory action states:

> In response to this argument, it is argued that all the elements of the claims are taught by the combined teachings of the cited references. Smedley teaches clearly, col.3, lines 36-47, glaucoma treatment by permitting aqueous to flow out of the anterior chamber of the eye through a stent to Schlem's canal with one end of the stent positioned in the anterior chamber and a second end positioned in the Schlem's canal. Regarding claim 25, the claim requires on end is in either anterior chamber or pars plana, and the reference teaches the anterior chamber. Peyman teaches implantable composition comprises antimicrobial agent in polymer matrix of polycaprolactone contained in a diffusible walled reservoir providing sustained release composition formulated to release non-toxic therapeutic amount of the antimicrobial agent over the time. The examiner believes that there is no lack of fact findings and each and every element of claim 11, and depending claims is taught either by the primary reference or by its combination with the secondary references as set forth in the previous office action. The present invention as a whole is taught by the combination of the references and would have been prima facie obvious in the meaning of USC 103(a).

Applicants disagree with the assertion made in the advisory action that every element of the claimed invention has been presented in the previous office action. Thus, Applicants do not believe that a proper prima facie obviousness rejection has been presented and Applicants respectfully request that the rejection be withdrawn and prosecution be reopened or the claims allowed.

The office action alleges that claims 24 and 32-34 are taught by Smedley; however, the office action has failed to present any facts as to where Smedley teaches a coating that covers the openings in the lumen. The office action has the burden to show where every element of the claims is taught either expressly or inherently by the references of record. The office action in rejecting these claims states:

> surrounding the device (col.10, lines 31-38, 60-65). The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that "the therapeutic agent can be loaded in interior location of the stent", would have suggested inner surface of the lumen of the stent or within the wall. Regarding claim 38, Smedley teaches, in col.9, lines 36-46, flow restricted member that can be a polymer that reads on claim 38.

The office action has not presented facts showing where the references of record teach claims 24 and 32-34 as indicated by the word "expected" in the rejection. A mere conclusory statement does not create a proper prima facie obviousness rejection and Applicants respectfully request that the rejection be withdrawn. ("'[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'")..... *KSR International co.*

v. Teleflex, Inc., 82 U.S.P.Q.2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

The office action alleges that Smedley teaches claim 38 and 39; however, Applicants do not believe that the facts as alleged is supported by the evidence found in Smedley. Claims 38 and 39 state, "wherein the device includes a focal **surrounding element** that can be altered to shrink and constrict the lumen." The office action cites col. 9, lines 36-46 which states,

> In modified embodiments, the flow-restricting member **72** (FIG. **5**) may be situated in any location within the device **31** and/or **31**A such that blood flow is restricted from retrograde motion. More than one flow-restricting member **72** mat also be efficaciously used, as needed or desired. The flow-restricting member **72** may, in some embodiments, be a filter made of a material selected from the following filter materials: expanded polytetrafluoroethylene, cellulose, ceramic, glass, Nylon, plastic, and fluorinated material such as polyvinylidene fluoride ("PVDF") (trade name: Kynar, by DuPont), and combinations thereof.

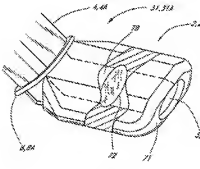

FIG. 5

Foremost, this passage states that the "flow restricting member 72 (FIG. 5) may be situated in any location within the device." (emphasis added) Claims 38 and 39 claim "a focal **surrounding element** that can be altered to shrink and constrict the lumen." Applicants do not believe that the flow restricting device will be able to shrink and constrict the lumen from the inside of the lumen. Furthermore, if the flow-restricting member shrinks Applicants do not believe that it will be able to "restrict[] retrograde motion [of blood flow]." If the flow restrictor is no longer able to restrict retrograde motion of blood flow then the proposed modification will render the prior art unsatisfactory for its intended purpose in violation of MPEP 2143.01. The advisory action further argues that:

> In response to this argument, it is argued that Smedley teaches, in col.9, lines 36-46, flow restricted member that can be a polymer that reads on claim 38. The claim does not recite any more specification of the flow restricting member. Further, the present claims are directed to a product, and the elements of the product are taught by the prior art in combination. The intended function of part of the device does not impart patentability to the claims.

However, neither the office action nor the advisory action has shown where "a focal surrounding element" is taught that "can be altered to shrink and constrict the lumen." The advisory action fails to account for the structural differences between the present invention and the references of record in rejecting claims 38 and 39, and it is these structural differences which allow the present invention to function as claimed. Therefore, Applicants do not believe that a proper prima facie obviousness rejection has been presented by the office action, and Applicants respectfully request that the rejection be withdrawn.

CONCLUSIONS

The office action has failed to present facts as to where every element of the claimed invention is found in the references of record. Thus, it is respectfully submitted that a prima facie case of obviousness has not been properly made and cannot be sustained based upon the references relied upon by the Examiner. Applicants, therefore, submit that claims 11 and 21-39 are patentable over the references of record. Allowance of claims 11 and 21-39 is respectfully requested.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

Dated: August 25, 2010

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